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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,413	07/31/2003	Robert E. Richard	02-264	4374
27774	7590	05/29/2007		
MAYER & WILLIAMS PC 251 NORTH AVENUE WEST 2ND FLOOR WESTFIELD, NJ 07090			EXAMINER HAGOPIAN, CASEY SHEA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/632,413	Applicant(s) RICHARD ET AL.	
	Examiner Casey Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 15 and 16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-14, 18-21 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 3/12/2007. Claims 1-16 and 18-26 are currently pending. Claims 1, 6 and 22 are currently amended; claims 23-26 are newly added; claim 17 has been cancelled; and claims 7-10, 15 and 16 have been withdrawn. In light of the newly added claims, applicant is reminded that the claims are examined to the extent that they read on the elected invention. That is, generic claims, such as claim 25 that read on both the elected and withdrawn inventions have only been examined in view of the elected invention.

### MAINTAINED REJECTIONS

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 11-14 and 18-21 stand rejected and newly added claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Kronfli et al. (GB 2271717**

**A).** Kronfli discloses polymeric biochemical compositions, particularly for medical uses, comprising a graft copolymer prepared via irradiation and one or more pharmaceutical compounds (abstract). The preferred copolymer is ethylene-vinyl acetate polymer grafted with acrylic and/or methacrylic acid (abstract). Poly(ethylene-vinyl acetate) has a Tg of -7°C (i.e. rubbery phase) as evidenced by PolySciences, Inc. and acrylic and

Art Unit: 1615

methacrylic acids have a Tg of 105°C and 228°C (i.e. glassy phase), respectively, as indicated in applicant's specification (paragraphs 0042 and 0043). Kronfli discloses that the compositions act as a polymeric reservoir for the rate controlled release of the pharmaceutical compound(s) (abstract). Kronfli further discloses medical devices including transdermal delivery reservoirs, ocular inserts, subcutaneous implants, catheters, and so on as well as particular pharmaceuticals including non-steroidal anti-inflammatories and cardio-vascular treatments (page 6, lines 16-25). It is noted that a catheter reads on "a shunt" as claimed by applicant as evidenced by the definition of "a shunt" found in Stedman's Medical Dictionary. The definition teaches that a shunt is synonymous with "a surgically implanted **catheter** for transport of fluid from a pleural space into the peritoneal cavity..." (see shunt, pleuroperitoneal at bottom of page 1). Kronfli also discloses the addition of additives and enhancing agents including polyalkylene glycols (page 1, lines 24-25; page 5, lines 7-15). It is noted that the limitation, "is adapted for", found in claims 18 and 20, is being treated as an intended use recitation. Structurally, said claims do not impart any additional limitations, thereby lacking any demonstration of patentable distinction between the prior art and the claimed invention. It should be further noted that the limitation "said graft copolymer has an elongation at break of at least 25% at ambient temperature" (claim 11) is considered a dependent property of the particular materials used. A product and its materials are inseparable and as such it is the position of the examiner that since Kronfli teaches the materials of claim 1, the materials also possess the particular dependent property "an elongation at break of at least 25% at ambient temperature". It should be

Art Unit: 1615

also noted that claim 13 is deemed a product-by-process claim due to the limitation, "is sterilized using a quantity of radiation effective to kill pathogens" and as such, determination of patentability is based on the product itself, not by the method in which it is made. The claim does not further limit the product itself. Thus it is for these reasons that the disclosures of Kronfli render the instant claims anticipated.

### ***Response to Arguments***

Applicant's amendment to claim 1 has rendered the rejections under 35 USC 102 and 103 over Hariharan moot. **Thus, the rejections of the claims 1-5, 11, 13, 14, 18 and 20 under 35 USC 102 and 103 over Hariharan have been withdrawn.**

Applicant's arguments with respect to the rejection under 35 USC 102 over Kronfli (see page 9) has been fully considered and is not persuasive. Applicant argues, "The incidental disclosure of 'catheters,' ocular inserts, vaginal rings, and subcutaneous implants (e.g., for contraception) does not rise to the level of an anticipation where it is lost within the entire disclosure, the subject of which is transdermal patches". The examiner respectfully disagrees. The MPEP states that patents are relevant as prior art for all they contain including non-preferred and alternative embodiments (see MPEP 2123). Kronfli clearly teaches other embodiments that include "insertable" and "implantable" devices as applicant pointed out above. Applicant's amendment has included additional limitations that recite particular medical devices including shunts. Stedman's Medical Dictionary teaches that a shunt is synonymous with "a surgically implanted **catheter** for transport of fluid from a pleural space into the peritoneal

Art Unit: 1615

cavity..." (see shunt, pleuroperitoneal at bottom of page 1). The catheter taught by Kronfli reads on the shunt as claimed by applicant. **Thus, for these reasons applicant's arguments are not persuasive and the rejection under 35 USC 102 over Kronfli is therefore maintained.**

### **NEW REJECTIONS**

The following rejections are in light of applicant's amendment submitted 3/12/2007:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-5, 11-14, 17-21 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (US 2002/0107330 A1).** Pinchuk teaches implantable or insertable medical devices coated with a composition comprising a biocompatible block copolymer and a therapeutic agent (Abstract). Said block copolymer comprises an elastomeric block and a thermoplastic block (Abstract), said elastomeric block is preferably a polyolefin (paragraph 0007) and said thermoplastic block is preferably methylmethacrylate, ethylmethacrylate, hydroxyethylacrylate, styrene and methylstyrene (paragraph 0008). Particular medical devices disclosed include catheters, guide wires, balloons, stents, and so on (paragraph 0015). Preferred

Art Unit: 1615

implantation or insertion sites for said medical devices are also disclosed and include coronary and peripheral vasculature, esophagus and so on (paragraph 0013). Said block copolymer can be in the form of a radial block or star-shaped copolymer, which are both known types of specific graft copolymers (paragraphs 0030 and 0032). Said medical device can further comprise a polymer or copolymer including a silicone, a siloxane polymer, and so on (paragraphs 0016-0017). Said therapeutic agents disclosed include antithrombotics agents, antiproliferative agent, anti-inflammatory agents, and so on (paragraph 0005). As indicated by applicant's specification, said polymers possess individual Tg's that fall into a rubbery or hard category (see pages 7-10 of Specification). Pinchuk teaches rubbery blocks (i.e., elastomeric) and hard blocks (i.e., thermoplastic) as well as the particular polymers claimed as indicated above. It is noted that the limitation "said graft copolymer has an elongation at break of at least 25% at ambient temperature" (claim 11) is considered a dependent property of the particular materials used. A product and its materials are inseparable and as such it is the position of the examiner that since Pinchuk teaches the materials of claim 1, the materials also possess the particular dependent property "an elongation at break of at least 25% at ambient temperature". It should be also noted that claim 13 is deemed a product-by-process claim due to the limitation, "is sterilized using a quantity of radiation effective to kill pathogens" and as such, determination of patentability is based on the product itself, not by the method in which it is made. The claim does not further limit the product itself. Thus it is for these reasons that the disclosures of Pinchuk render the instant claims anticipated.

***Pertinent Art***

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Chen et al. (US 2003/0039689 A1) teaches a polymer-based, sustained release drug delivery system (title; abstract). Chen specifically exemplifies a coating comprising a poly(ethyl acrylate and methyl methacrylate) copolymer and 5-fluouracil, an anti-neoplastic drug (example 9). Chen further teaches that the coatings may be applied to medical devices including catheters vascular grafts and stents (paragraphs 0037-0038).

Hariharan discloses graft copolymers used as drug delivery devices comprising a backbone containing copolymerized acrylic acid and optionally, vinyl monomers, and side chains preferably containing polymers from the classes of polybutylene, poly(ethyleneoxide/propyleneoxide), polycaprolactum, polysaccharide, and polyamide polymers (abstract; column 2, lines 34-50). Hariharan specifies that an active medicament is contained in the drug delivery devices, specifically in the same polymeric layer, and also some advantages of the copolymer materials used in terms of drug loading (column 1, lines 47-50; column 9, lines 20-22). Hariharan specifically discloses that the acrylic/vinyl polymeric backbone has a glass transition ( $T_g$ ) of  $-30^{\circ}\text{C}$  or lower (i.e., a "low  $T_g$ " or rubbery phase) (column 2, lines 59-61) and exemplifies various backbone polymer formulations having  $T_g$ 's of no more than  $-38^{\circ}\text{C}$  (column 7, lines 15-45). Hariharan further discloses specific polymers suitable for grafting onto the backbone (i.e. side chain polymers) including poly(vinyl chloride), poly(n-vinyl



Art Unit: 1615

pyrrolidone) and poly(acrylamide) (column 4, lines 25-39); all of which posses a Tg of 50°C or higher (i.e., a "high Tg" or hard phase).

### ***Allowable Subject Matter***

Claims 6 and 22 appear to be free of the art and may be allowable pending a patentability conference.

### ***Conclusion***

Claims 1-5, 11-14, 18-21 and 24-26 have been rejected. Claim 23 is objected to as being dependent upon a rejected base claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

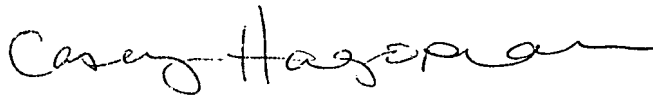
Art Unit: 1615

***Correspondence***

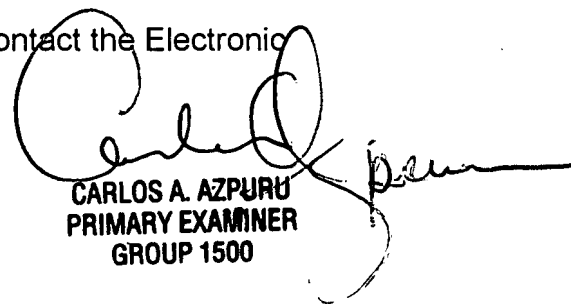
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Casey Hagopian  
Examiner  
Art Unit 1615



CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500